EUROPEAN COMMISSION

Brussels, 29.1.2010
C(2010)706

COMMISSION DECISION

of 29.1.2010

on the renewal of the marketing authorisation for the medicinal product for human use "Azopt - Brinzolamide", granted by Decision C(2000)576

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Alcon Laboratories (UK) Ltd., on 16 June 2009, under Article 14(2) of Regulation (EC) No 726/2004 with a view to the renewal of the marketing authorisation for the medicinal product "Azopt - Brinzolamide"

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 28 June 2009,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2], and in particular Article 61(3) thereof,

Whereas:

(1) On the basis of a re-evaluation by the Agency of the risk-benefit balance following the consideration of a consolidated file, it appears that the medicinal product "Azopt - Brinzolamide", entered in the Community register of medicinal products under number(s) EU/1/00/129/001-003 and authorised by Commission Decision C(2000)576 of 9 March 2000, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) The marketing authorisation which expires on 10 March 2010 should therefore be renewed.

(3) Alcon Laboratories (UK) Ltd. submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 311, 28.11.2001, p. 67.
3 OJ L 311, 28.11.2001, p. 67.

package leaflet, which has (have) not yet been included in Decision C(2000)576 of 9 March 2000.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2000)576 of 9 March 2000 which expires on 10 March 2010 is renewed.

Article 2

Decision C(2000)576 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/267/N/33	IIIAB (EU/1/00/129/001-003)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

This Decision is addressed to Alcon Laboratories (UK) Ltd., Pentagon Park, Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom.

Done at Brussels, 29.1.2010

For the Commission
Heinz ZOUREK
Director-General